Clinical Research Report

Journal of INTERNATIONAL MEDICAL RESEARCH

Journal of International Medical Research
2018, Vol. 46(10) 4129–4139

DOI: 10.1177/0300060518786902
journals.sagepub.com/home/imr
SAGE

The risk management of medical device-related pressure ulcers based on the Australian/ New Zealand Standard

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Abstract

Objective: To analyse medical device-related pressure ulcer (MDRPU) management modes and their possible risks and provide references to treat MDRPUs.

Methods: The Australian/New Zealand Standard (AS/NZS) 4360:2004 risk management standard is the first national risk management standard in the world. Zhongshan Hospital adopted the standard to establish risk management modes to improve the MDRPU risk management process and to register, assess and analyse the key risks for MDRPUs. Eight risk types were identified and registered: organization management risk, environment risk, patient safety risk, human resource risk, infection risk, occupational safety risk, legal risk and reputational risk.

Results: Following the implementation of the AS/NZS 4360:2004 risk management standard in our institution, the organization management risk value decreased from 25 to 5; the environment risk value decreased from 25 to 5; the patient safety risk value decreased from 20 to 3; the human resource risk value decreased from 16 to 4; the infection risk value decreased from 9 to 1; the occupational risk value decreased from 9 to 6; the legal risk value decreased from 9 to 4; and the reputational risk value decreased from 12 to 2.

Conclusion: The AS/NZS 4360:2004 risk management standard was effective in managing the risk of MDRPUs.

Keywords

Medical device-related pressure ulcers (MDRPUs), AS/NZS 4360/2004 standard, risk management

Date received: 30 January 2018; accepted: 29 May 2018

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Introduction

Risk management is a formalized proactive process that has been used in a range of occupational settings, including firefighting and mining, to reduce workplace hazards and injuries.[1] Competition in the medical market is becoming increasingly fierce. The Chinese Ministry of Health is increasingly attentive to risk management in the medical process, as hospital managers should effectively and comprehensively manage medical risks, weigh and evaluate risks and benefits, and select suitable risk control measures in accordance with the hospital's status in order to cut medical risk losses and safeguard the common interests of doctors and patients. Medical device-related pressure ulcers (MDRPUs) arise when *in vitro* medical devices produce pressure, causing local damage to the skin and/or subcutaneous tissue that corresponds with the shape of the device.[2] An increasing number of modern medical devices have been widely applied to clinical patients. However, if the device does not reach the designated position, if the adjustment of a tube such as endotracheal intubation tube is unsuitable, or if the selection and use of protective dressings for pressure ulcers is inappropriate, local compression and ischaemia-hypoxia damage can result. Because of the above risk factors, hospital nursing managers analyse and process potential risks by using risk management theory and establishing risk prevention and resolution mechanisms.[3] This report describes and uses the Australian/New Zealand Standard (AS/NZS) 4360:2004 risk management standard to formulate risk management plans.[2]

Patients and methods

Patient population

Zhongshan Hospital, which is affiliated to Xiamen University, was built in 1928. The hospital has 2672 faculty members and 2500 authorized beds. The hospital treats 2.8 million outpatients and emergency patients every year. There are nearly 60 000 inpatients each year and 18 000 surgeries are performed per year. There are approximately 8000 patients that are at risk for pressure ulcers. As a consequence of the aging population and the fact that medical devices are used widely in this hospital, the incidence of pressure ulcers at the sites where medical devices contact the skin continues to increase. A cross-sectional study with 2178 patient cases noted that MDRPUs account for 34.5% of all pressure ulcers.[3] Nurses should pay close attention to the problems related to pressure ulcers during the use of medical devices so that they can achieve comprehensive prevention and improve overall quality of pressure ulcer nursing. The AS/NZS 4360:2004, an international standard for risk management, was the world's first national standard.[2] A risk management review (Figure 1) was involved in hospital skin management and was used to develop the risk management plan of MDRPUs (Figure 2).

Establishing the environment

Establishing the risk environment avoids the basic parameter of risk management; and fosters and encourages an environment where managing risk is accepted as each person's day-to-day responsibility. Establishing this environment also sets the ranges for other parts of the process of risk management.[4] Each possible risk of MDRPUs must be managed by hospitals internally and externally.

Establishing a strategic environment

An MDRPU can occur in any department and for patients of any age who use medical devices. To prevent MDRPUs, key hospital departments need to provide services for

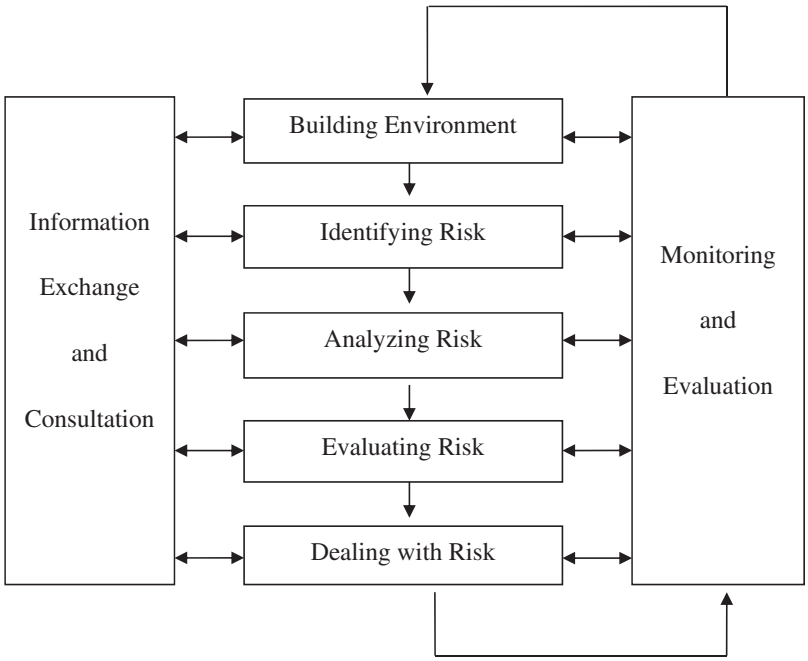

Figure 1. Risk management review for medical device-related pressure ulcers based on the Australian/New Zealand Standard 4360:2004 risk management standard used to formulate risk management plans.

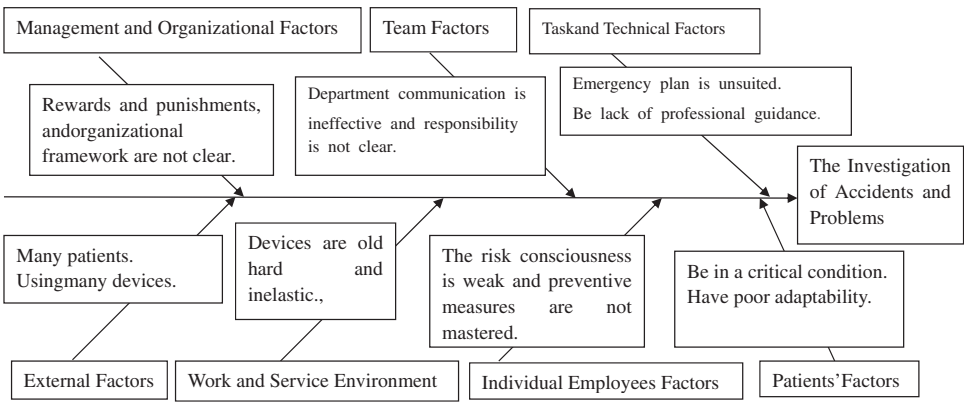

Figure 2. Fishbone diagram analysis for medical device-related pressure ulcers based on the Australian/New Zealand Standard 4360:2004 risk management standard used to formulate risk management plans.

such patients. The hospital establishes a 'risk management committee for MDRPUs', which includes a department containing an equipment division, a purchasing department, an information department, a nursing department, an infection control section and a chronic wound nursing specialist. These individuals are responsible for organizing, leading and making important decisions. The supervisors of each department oversee

risk management tasks and jointly identify risks, analyse risks and treat risks within their related departments. The staff of every department takes charge of risk management and their own specific tasks.

Establishing the organization environment

To build a risk management system addressing MDRPUs, an 'internal risk management organization for medical device-related pressure ulcers' must be established in hospitals. The director of nursing, an international enterostomal therapist, a head nurse and professional teams, each of whom are put in charge of hospital pressure ulcer management, are responsible for putting risk management procedures into practice. At the same time, these people must assess potential risk factors in every department, finish the risk evaluation and develop emergency plans and work procedures.

Establishing the risk management principles

The key to establishing risk management principles for MDRPUs is as follows: updating the idea while putting prevention first, building the idea with the help of hospital safety culture, and integrating risk management concepts to undertake the work.

Establishing a risk management responsibility system

In 'the internal risk management committee for MDRPUs', when all levels of the management system perform tasks related to the risk publishing system, their responsibility must be definite. The chairman of the committee should be somebody responsible for risks. However, each team leader is responsible for managing department-related activities and personnel assignments, and he or she undertakes direct responsibility for each specific task and completing it correctly. When accidents happen, it is necessary to first check the entire risk prevention system committee in order to determine who takes charge of completing every necessary task.

Establishing a risk assessment and standardization system

Any standardization system that applies to risk assessment and risk identification should conform to national regulations, including an advice on Pressure Ulcer Nursing in China (2013).[5] In addition, the National Pressure Ulcer Advisory Panel participated in and formulated the Pressure Ulcer Prevention and Treatment Guidance (2014).[6] The Hospital Pressure Ulcer Management Handbook should also be followed. Furthermore, the Nursing Services Core System (2014) in the hospital office automation net contains the Shift Relief System, Consultation System, Reporting System for Nursing Adverse Events, Reporting System for Rescuing Critical Patients, and the Using and Managing System for Usual Equipment, Device and Rescue Goods. Combined with the process of hospital work instructions, we can divide the operational risks into eight independent risk types as follows: management risk, environment risk, patient safety risk, human resource risk, infection risk, occupational safety risk, legal risk and reputational risk. In addition, these risks may be separated into four levels according to the likelihood of accidents and serious consequences. They are low risk, moderate risk, high risk and extreme risk. There are three acceptability levels: acceptable, partly acceptable and unacceptable. At the same time, we discovered that some risks should be analysed to reduce or eliminate them, including the high-risk patient's websitemark and bedsidemark, which are used as visual reminders for doctors and nurses that the patient is at risk of MDRPUs, the predilection site mark, medical device usage

time and quantity, computer network, preventive dressing and staff.

Risk identification

On the basis of the eight types of identification risks and the abovementioned key factors, there are several ways of identifying existing or potential risk and conducting the next step of risk analysis and risk elimination procedures. These methods include auditing examinations, brainstorming, informal discussions, group discussions, evaluating current and previous data, root cause analysis and standardized check table of MDRPUs.

Risk analysis

The levels of eight risk consequences were analysed using a risk quantification matrix (Table 1). Many patients live by relying on medical devices. When there is local oedema at the site where the medical device is used, tissue hypoxia around the circulatory disturbance (e.g. sepsis and using angiotonics), metabolic status change, trophic disturbance, sensory disturbance, general weakness, use of more devices and longer hospitalizations will increase the risk of MDRPUs after using medical devices.[7] Thus, healthcare professionals are on high alert for MDRPUs. The longer the device is used, the higher the risk of MDRPUs. For example, one study analysed the risk factors for neck collar-related pressure ulcers among patients with cervical spine injury using multiple regression analysis and discovered that if the time during which the device was used was extended by 1 day, the risk of pressure ulcers increased by 66%.[8] Another study in infants reported that when the usage time of medical devices exceeded 3 days, the risk of skin injury was higher.[9] More than 5 days of use of continuous positive airway pressure for newborns is a risk factor for MDRPUs.[9]

The length of stay can reflect the duration of use of the medical device. One study reported that on the eleventh day of the patients' stay in the intensive care unit (ICU), the incidence of MDRPUs was seven-times higher than on the first day.[10] A length of stay greater than 14 days for children in the ICU is a risk factor for MDRPU.[11] Another risk factor is the number of devices being used. A previous study demonstrated that if patients used more than one kind of device at the same time, the risk of pressure ulcers increased 2.4 times.[3]

Table 1. Risk quantification matrix used to analyse the levels of eight risk consequences for medical device-related pressure ulcers.

	Consequence score				
Likelihood score	Insignificant 1	Minor 2	Moderate 3	Major 4	Extreme 5
Almost certain – 5	5	10	15	20	25
Likely – 4	4	8	12	16	20
Possible – 3	3	6	9	12	15
Unlikely – 2	2	4	6	8	10
Remote–1	1	2	3	4	5

Risk quantification matrix: five levels of 'Likelihood' from remote to almost certain according to the possibility of the risk occurring. The severity of the result is divided into five grades from insignificant to extreme, the value of which is equal to the 'Likelihood' score multiplied by the 'Consequence score': 1–5, low risk; 6–15, medium risk; 16–25, high risk.

The physical characteristics of medical devices, such as their material and design, can influence the incidence of MDRPUs. The less elastic or harder the device is, the greater the risk. It is easier to create friction and inflict pressure on tissue when the device is hard. If the design of the device makes it easy to directly put pressure on a patient's skin, then it is easier for MDPRUs to occur.[8] The consequences were divided into insignificant (level 1), minor (level 2), moderate (level 3), major (level 4) and extreme (level 5) (Table 1). Some cases of MDRPU scan become quite severe and costly (Table 2), and the likelihood of those events is separated into almost certain (level 5), likely (level 4), possible (level 3), unlikely (level 2) and almost impossible (level 1) (Table 3).

Risk assessment

The risk analysis and risk assessment systems, as previously mentioned, can be used to determine whether the risk should be accepted or eliminated. Risks regarded as low or acceptable can have minimal checks according to synchronous monitoring and periodic needs. It is necessary to eliminate or avoid unacceptable risks. We set up a risk register to record these standards (Table 4).

Table 2. Risk consequence assessment in terms of financial impact and implications for the patient for medical device-related pressure ulcers.

Level	Description	Financial impact	Patient impact
1	Insignificant	<30000CNY	Adverse events lead to insignificant damage, but patients do not need first aid
2	Minor	30000–200000CNY	Patients with minor damage or disease need emergency treatment, and the length of stay extends to 3 days
3	Moderate	200000–500000CNY	Patients with moderate damage need medical treatment, and the length of stay extends to 3–8 days
4	Major	500000–1000000CNY	Patients have major damage, long-term disability or disability requiring medical treatment
5	Extreme	>1000000CNY	Accidents lead to death or major permanent loss of function

CNY, Chinese yuan.

Table 3. Risk likelihood assessment for the occurrence of medical device-related pressure ulcers.

Likelihood	Actual occurrence frequency	Probability
Almost certain	At least 1 time a month	99%
Likely	At least 1 time every 2 months	90%
Possible	At least 1 time every 1–2 years	50%
Unlikely	At least 1 time every 2–5 years	10%
Almost impossible	At least 1 time every 5 years or more than 5 years	1%

Table 4. Risk register for medical device-related pressure ulcers.

Risk number	Risk type	Risk description	Existing or potential risk	Risk likelihood	Risk consequence	Initial value-at-risk	Risk order
1	Organization management risk	Because the organization management frame is not clear and the prevention process has not been formulated, there is an increased incidence of medical device-related pressure ulcers	Existing	5	5	25	1
2	Environment risk	Because some medical devices are old and there is no technician tracking of new medical devices, an increased incidence of medical device-related pressure ulcers may occur	Existing	5	5	25	1
3	Patient safety risk	Because prevention technology is of poor quality and medical staff are indifferent, patients' skin or mucosa may be crushed	Potential	4	5	20	1
4	Human resource risk	Because of increased workload and fewer nurses unable to regularly check the skin in contact with the medical device, there is an increasing incidence of medical device-related pressure ulcers	Existing	4	4	16	1
5	Infection risk	Because the infection department does not update in time, there are missing high-risk warning signs. Therefore, because of a lack of warnings, the incidence of medical device-related pressure ulcers increases	Potential	3	3	9	2
6	Occupational safety risk	Because the hospital staff have poor awareness of safety culture and are afraid of punishment, pressure ulcers are more likely to be concealed and go unreported	Existing	3	3	9	2

(continued)

Table 4. Continued.

Risk number	Risk type	Risk description	Existing or potential risk	Risk likelihood	Risk consequence	Initial value-at-risk	Risk order
7	Legal risk	There are no clinical guidelines regarding new prevention dressing, which leads to misuse, abuse and disuse	Existing	3	3	9	2
8	Reputational risk	Nurses feel depressed and workless actively, until they become unstable	Potential	3	4	12	2

Risk treatment

We have also created a brief description of all types of risk likelihoods by properly reducing risk strategies and leading the achievement of these strategies (Table 5).

Results

Following the implementation of the AS/NZS 2004 risk management standard in our institution, the organization management risk value decreased from 25 to 5; the environment risk value decreased from 25 to 5; the patient safety risk value decreased from 20 to 3; the human resource risk value decreased from 16 to 4; the infection risk value decreased from 9 to 1; the occupational risk value decreased from 9 to 6; the legal risk value decreased from 9 to 4; and the reputational risk value decreased from 12 to 2.

Discussion

Risk communication and consultation are important ways to manage risk. Effective communication and consultation lay the foundation for risk identification and analysis systems. Communication not only involves communication between departments but also communication among internal staff members. Risk management requires that everyone participates. It is very important for staff to be trained, to communicate with higher departments and analyse and eliminate risk factors. Effective internal and external information communication is very important and ensures that individuals are responsible for implementing risk management and maintaining a vested interest in understanding the foundation of decisions and why special measures are taken.

Risk management is a process of continuous improvement. Therefore, it is necessary to monitor and check the consequences of any new risk management system at fixed periods. Adverse events without a punishment reporting system leads to a vicious cycle of risk management. Evaluation is a part of the entire risk treatment plan and it can ensure that management plans are appropriate. By identifying residual risks and evaluating risk management or control plans, the incidence of MDRPUs can be effectively reduced. Risk management committees on medical devices should hold a risk management meeting every 3 months and encourage every department to conduct self-plans. In addition, every department should hold a working risk management meeting every month. Each department should also check risks and assist in operations daily, report MDRPUs occurring in the department in a timely manner, organize discussions within the department weekly, and encourage staff members in nursing departments

Table 5. Risk treatment plan for medical device-related pressure ulcers.

Risk number	Risk description	Reduce risk strategy	Implementation schedule	Implementation principal	Residual risk level			
					Consequence	Likelihood	Existing value-at-risk	Existing risk level
1	Because the organization management frame is not clear and the prevention process is not formulated, an increase occurs in the incidence of medical device-related pressure ulcers	Clear organization management framework; organize training every month; formulate prevention procedure	At once	Hospital, nursing department	5	1	5	3
2	Because some medical devices are old, and there is no technician tracking new medical devices, an increased incidence of medical device-related pressure ulcers occur	Expand investment, replace in batches; track new device producers; clear risk of medical device-related pressure ulcers	Long-term	Medical device purchasing department	5	1	5	3
3	Because prevention technology is of poor quality and medical staff are indifferent, patients' skin or mucosa is crushed	Evaluate risk of pressure ulcers; establish prevention procedures; enhance health education; check compressive skin at least two times every shift; protect high-risk locations	Long-term	Department head nurse, chronic wounds specialist nurse	3	1	3	3
4	Because of the increasing workload and fewer nurses able to regularly check the skin in contact with medical devices, an increase in the incidence of	Increase the nursing human input, achieve the ratio of beds to nurses, especially in the ICU	Long-term	Human resources department, nursing department	2	2	4	3

(continued)

Table 5. Continued.

Risk number	Risk description	Reduce risk strategy	Implementation schedule	Implementation principal	Residual risk level			
					Consequence	Likelihood	Existing value-at-risk	Existing risk level
	medical device-related pressure ulcers occurs							
5	Because the infection department does not update in time, there are missing high-risk warning signs. Therefore, because of a lack of warnings, the incidence of medical device-related pressure ulcers increases	Increase high-risk warning signs regarding medical device-related pressure ulcer; set up cue card above bed	At once	Infection department	1	1	1	3
6	Because the hospital staff have a poor awareness of the safety culture and they are afraid of punishment, pressure ulcers are concealed and go unreported	Encouragement; no punishment; report adverse events	Long-term	Nursing department	3	2	6	3
7	Because there are no clinical guidelines regarding new prevention dressing, misuse, abuse and disuse occurs	Purchase prevention pressure ulcer dressing according to unit needs; indication of new dressing use; frequency of dressing replacement	Long-term	Purchase department, nursing department	2	2	4	3
8	Because nurses are under fire, they may feel depressed and work less actively until they become unstable	Strengthen nurse specialist knowledge training; establish all kinds of protection systems; establish nurse care organization	Long-term	Nursing department	1	2	2	3

and chronic wound care departments and those in charge of project improvement to also participate in the discussion.

In conclusion, the AS/NZS 4360:2004 risk management standard lists a set of definitions to describe risk management in the standard process.[2] In clinical practice, it allows clinical nurses to provide medical services according to current best practices. In performance and skill management, it allows managers and clinical nurses to have academic skills and methods that can provide safe and high-quality services. In event and complaint management, this standard can identify, report and analyse patient safety and quality events and use this information to improve the security system. Actively considering the most important risk of an organization or a service, identifying opportunities and threats, improving the analysis of current treatment strategy effectiveness, and establishing positive and reliable bases for decision making while planning to ensure that the risk owner is responsible.

Declaration of conflicting interests

The author declares that there are no conflicts of interest.

Funding

This work was supported by Xiamen Science and Technology Project (grant no. 3502Z20164025).

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